were approved under an emergency approval for 6-months and included a new requirement for Tribes or Tribal organizations to provide that charging fees and recovering costs will not be permitted.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review-Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The final rule within 45 CFR part 309, published in the **Federal Register** on March 30, 2004 at 69 FR 16638, contains a regulatory reporting requirement that, in order to receive funding for a Tribal IV–D program, a Tribe or Tribal organization must submit a plan describing how the Tribe or Tribal organization meets or plans to meet the objectives of section 455(f) of the Social Security Act, including establishing paternity; establishing, modifying, and enforcing support orders; and locating noncustodial parents. The plan is required for all Tribes requesting funding; however, once a Tribe has met the requirements to operate a comprehensive program, a new plan is not required annually unless a Tribe makes changes to its title IV–D program. If a Tribe or Tribal organization intends to make any substantial or material changes, a Tribal IV–D plan amendment must be submitted for approval. Tribes and Tribal organizations must have an approved plan and submit any required plan amendments in order to receive funding to operate a Tribal IV–D program. Through an emergency approval request, OCSS included a new requirement for Tribes and Tribal organizations to provide that charging fees and recovering costs will not be permitted. This is due to the Final Rule on the Elimination of the Non-Federal Share published on February 12, 2024 (see 89 FR 9784). Tribes and Tribal organizations that charge fees and recover cost must submit a plan amendment demonstrating compliance with the proposed new requirement, in accordance with 45 CFR 309.35(d). This is a one-time submission. Only three Tribal child support programs report data on the collection of fees and recovered costs. This request is to extend approval with no changes.

Respondents: Tribes and Tribal Organizations.

Burden Estimates

The following burden estimates include new burden associated with the change in requirement, as well as existing burden under OMB #: 0970–0218.

Instrument	Total number of respondents	Total number of responses per respondent (over three years)	Burden hours per response	Total burden hours (over three years)	Annual burden hours
45 CFR 309—New Plan	10	3	480	14,400	4,800
45 CFR 309—Plan Amendment	60	*2	105	18,900	6,300
45 CFR 309—Plan Amendment—Charging fees and recovering	3	1	3	9	3
Estimated Burden Hours and Costs				33,309	11,103

*This estimate is based on an average number of about 2 amendments submitted per year per Tribe, but that does vary annually and by Tribe.

Authority: Title IV–D of the Social Security Act; 45 CFR 309.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–03968 Filed 2–26–24; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–2217]

Determination of Regulatory Review Period for Purposes of Patent Extension; Rybrevant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Rybrevant and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by April 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 26, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. eastern time at the end of April 29, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–E–2217 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; RYBREVANT.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product Rybrevant (amivantamab-vmjw). Rybrevant is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. Subsequent to this approval, the USPTO received a patent term restoration application for Rybrevant (U.S. Patent No. 9,593,164) from Janssen Biotech, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 21, 2022, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of Rybrevant represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Rybrevant is 1,284 days. Of this time, 1,105 days occurred during the testing phase of the regulatory review period, while 179 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* November 16, 2017. The applicant claims November 19, 2017, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 16, 2017, which was the first date after

receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* November 24, 2020. FDA has verified the applicant's claim that the biologics license application (BLA) for Rybrevant (BLA B761210) was initially submitted on November 24, 2020.

3. *The date the application was approved:* May 21, 2021. FDA has verified the applicant's claim that BLA B761210 was approved on May 21, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 546 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–03961 Filed 2–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Ryan White HIV/AIDS Program Core Medical Services Waiver Form, OMB No. 0906–0065—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 29, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Ryan White HIV/AIDS Program Core Medical Services Waiver Form, OMB No. 0915–0065—Revision

Abstract: In accordance with sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act, recipients are required to spend not less than 75 percent of funds on core medical services for individuals with HIV identified and eligible under the statute, after reserving permissible amounts for administrative and clinical quality management (CQM) costs. The statute also grants the Secretary of Health and Human Services authority to waive this requirement for a Ryan White HIV/AIDS Program (RWHAP) Part A, B, or C recipient if certain requirements are met, and a waiver request is submitted to HRSA for approval.

As currently implemented by HRSA, to be approved, (1) core medical services must be available and accessible to all individuals identified and eligible for the RWHAP in the recipient's service area within 30 days. This access must be without regard to payer source, and without the need to spend at least 75 percent of funds remaining from the recipient's RWHAP award after statutorily permissible amounts for administrative and CQM costs are reserved; (2) the recipient must ensure there are no AIDS Drug Assistance Program (ADAP) waiting lists in their service area; and (3) a public process to obtain input on the waiver request must have occurred. This process must seek input from impacted communities including clients and RWHAP-funded core medical services providers on the availability of core medical services, and the decision to request the waiver. The public process may be a part of the same one used by recipients to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of need, public planning, and/or needs assessment processes. RWHAP Parts A, B, and C core medical services waiver requests must include funds awarded under the Minority AIDS Initiative. Core medical services waivers are effective for a 1-year period.

The process for RWHAP Parts A, B, and C grant recipients to request a waiver of the minimum expenditure amount requirements for core medical services is outlined in Policy Notice 21–01, Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement.

HRSA proposes to modify the one-page form to include the proposed percentages of HIV service dollars allocated to core medical and support services. Under the proposed changes, a field will be added to the form to capture the proposed percentages. This information will inform HRSA whether recipients are able to meet the statutory requirements in sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act and will clarify what proposed portion of funds will be allocated to core medical and support services. Minor changes will also be made to the form to increase readability.

Summary of Proposed Changes: Sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act requires recipients to spend not less than 75 percent of funds on core medical services after reserving statutorily